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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,692	08/14/2001	Jim J. McGhan	011111	3354

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Michael G. Petit
P. O. Box 91929
Santa Barbara, CA 93190-1929

EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 03/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.



Office Action Summary

Application No.

09/931,692



Applicant(s)

MCGHAN, JIM J.

[Signature]

Examiner

Cheryl Miller

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-- Th MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,4,6,8 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,4,6,8 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 2,4,6,8 and 11 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention: species 1 drawn toward figures 3, 6, and 7, species 2 drawn toward figures 4, 8, and 9, and species 3 drawn toward figure 10.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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During a telephone conversation with Michael Petit (registration number 30,795) on February 19, 2003 a provisional election was made without traverse to prosecute the invention of species 1, claims 2, 4, 6, 8, and 11. Affirmation of this election must be made by applicant in replying to this Office action.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Michael Petit on February 19, 2003. Amendment was made in order to make claim 11 readable on species 1.

The application has been amended as follows:

Claim 11 has been replaced with --The hybrid medical implant of claim 2, wherein said bioabsorbable portion comprises an antibiotic--.

Response to Arguments

Applicant's arguments with respect to claims 1-13 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 2, 4, 6, 8, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Referring to claim 2, it is unclear as to if "a plurality of particles of a bioabsorbable material" is the same or in addition to "a bioabsorbable portion". If the two bioabsorbable portions are intended to be the same, it is suggested to clarify. For example, change "a plurality of particles" to --wherein the bioabsorbable portion comprises a plurality of particles--. It is also unclear as to if "a nonbioabsorbable elastomeric substrate" is the same or in addition to "an elastomeric, nonbioabsorbable core portion". If the two nonbioabsorbable portions are intended to be the same, it is suggested to clarify. For example, change "a nonbioabsorbable elastomeric substrate" to recite --wherein said elastomeric, nonbioabsorbable core portion comprises a substrate--. Claims 4, 6, 8, and 11 depend upon claim 2 and inherit all problems associated with the parent claim.

Claim 2 recites the limitation "said outer surface of said hybrid medical implant" in line 5. There is insufficient antecedent basis for this limitation in the claim. An outer surface of the implant has not been previously claimed, only an outer surface of the core portion has been claimed. It is unclear as to if the core or implant outer surface is intended to have an irregular topography.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2, 4, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoffman, Jr. et al. (USPN 5,197,977). Hoffman discloses a hybrid implant (10) comprising an elastomeric nonbioabsorbable core substrate portion (12; col.3, lines 12-16) and a plurality of bioabsorbable particles (16; collagen fibrils) embedded in the substrate (col.3, lines 18-20), wherein an outer surface has an irregular topography (fig.1). Hoffman discloses a core portion (12) comprising a fluid filled elastomeric shell (upon implantation, the core, graft in this case, is filled with blood). Hoffman discloses the bioabsorbable portion (16) comprising an antibiotic (col.2, lines 38-41; col.5, lines 59-69; col.6, lines 1-3).

Claims 2, 4, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by De Goicoechea et al. (USPN 5,383,927). De Goicoechea discloses a hybrid implant (10) comprising an elastomeric nonbioabsorbable core substrate portion (base material; col.3, lines 12-18, 44-48) and a plurality of bioabsorbable particles (18, collagen; col.5, lines 9-11) embedded in the substrate (col.4, lines 3-5, 15-18, 34-38), wherein an outer surface has an irregular topography (fig.1A, 22). Hoffman discloses a core portion comprising a fluid filled elastomeric shell (upon implantation, the core, graft in this case, is filled with blood). Hoffman discloses the bioabsorbable portion comprising an antibiotic (24, heparin).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 4, 6, 8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quaid (USPN 4,889,744) in view of Goldstein et al. (USPN 6,143,037). Referring to claims 2 and 11, Quaid discloses an implant comprising an elastomeric nonbioabsorbable core portion (16) having an outer surface with an irregular topography (22). Quaid does not disclose however, an additional bioabsorbable portion having an antibiotic, affixed to the core portion. Goldstein teaches in the same field of implants, bioabsorbable particulate coatings on implants (col.1, lines 5-8; col.5, lines 54-57, 64-67) for the purpose of increase tissue affixation, eventual detachment, and drug (antibiotic) release (col.6, lines 42-52; col.19, lines 27-40, 44-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the implant of Quaid with Goldstein's teaching of coating implants with a plurality of particles of bioabsorbable material, in order to provide a textured implant with a bioabsorbable portion embedded in the surface topography of the implant core, in order to increase tissue affixation, eventual detachment, and to add the ability to timely release drugs/antibiotics.

Referring to claims 4, 6, and 8, Quaid discloses a core portion comprising a fluid-filled elastomeric shell (saline, col.7, lines 15-16, 21) or a solid elastomeric body (gel, col.7, lines 13, 20), wherein the core portion comprises silicone (col.6, lines 14-16).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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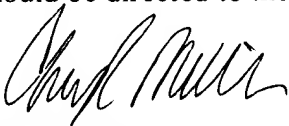
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

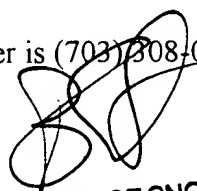
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Cheryl Miller
March 5, 2003


BRUCE SNOW
PRIMARY EXAMINER